DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 16, 2015

OrSense Ltd.
c/o Mr. Mark Heller
Consultant
Goodwin Procter LLP
901 New York Avenue, N.W.
Washington, D.C. 20001

Re: K142209
Trade/Device Name: NBM-200 Pulse Oximeter and Hemoglobin Monitor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, GLY
Dated: December 17, 2014
Received: December 18, 2014

Dear Mr. Heller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):__K142209_____

Device Name: NBM-200 Pulse Oximetry and Hemoglobin Monitor device

Indications for Use:

The NBM-200 is a portable Hemoglobin and oximetry monitor. It non-invasively spot checks and displays Hemoglobin (Hb), estimated Hematocrit (Hct) values, functional saturation of arterial oxygen hemoglobin (SpO2), and pulse rate (PR). These parameters can be displayed periodically for patient monitoring.

The monitor estimates Hct via a calculation based on the Hb measurement for normal hemoglobin values (11 to 17 g/dl) only and abnormal values will not be displayed. It is intended for use by trained medical personnel, with adult individuals, in non-critical clinical and non-clinical settings (e.g. non-critical settings in hospitals, hospital-type facilities, mobile environments, clinics, physician offices and ambulatory surgery centers). In this context, non-critical means patient examination settings where continuous monitoring is unnecessary. Non-critical environments exclude, for example, intensive care units.

Prescription Use __√___ (Per 21 C.F.R. 801 Subpart D)	OR	Over-The-Counter Use___ (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

— —

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

NBM-200 PULSE OXIMETRY DEVICE

510(k) Number K142209_____

Applicant's Name: OrSense Ltd.
17 Ha'Mefalsim St.,
Kiryat Arie,
Petah Tikva, 49514
Israel 4900302
Tel. + 972-3-7404900
Fax. +972-3-7404909
E-mail: Aharon.weinstein@orsense.com

Contact Person: Mark A. Heller
Kristin Davenport
Goodwin Procter LLP
901 New York Avenue, N.W.
Washington D.C. 20001
USA
Tel. (202) 346-4107
Fax. (202) 346-4444
e-mail: mheller@goodwinprocter.com or
Kdavenport@goodwinprocter.com

Date Prepared: August 7, 2014

Trade Name: NBM-200 Pulse Oximeter and Hemoglobin Monitor

Device Common or Usual Names: Pulse Oximeter

Classification Name: Oximeter

Classification: 21 CFR § 870.2700 (Product Code DQA)
21 CFR § 864.7500 (Product code GLY)

Predicate Device:

The NBM-200 Pulse Oximeter and Hemoglobin Monitor device is substantially equivalent to the FDA cleared NBM 200MP Pulse Oximeter and Hemoglobin Monitor (K124041) manufactured by OrSense Ltd.

Device Description:

The NBM-200 is a portable Hemoglobin and oximetry monitor, based on occlusion spectroscopy technology, for non-invasive spot checking of hemoglobin (Hb), estimated Hematocrit (Hct), SpO2 and pulse rate.

The NBM-200 includes a reusable ring-shaped sensor probe that fits on the patient's finger, and a portable desktop monitor that calculates and displays the measurement result.

The sensor probe consists of a multi-wavelength optical measuring system and inflatable cuff employing pneumatic tissue manipulation. Blood flow in the finger can be briefly occluded and the resulting changes in its optical behavior are analyzed to provide accurate measurements of Hb.

Intended Use / Indication for Use:

The NBM-200 is a portable Hemoglobin and oximetry monitor. It non-invasively spot checks and displays Hemoglobin (Hb), estimated Hematocrit (Hct) values, functional saturation of arterial oxygen hemoglobin (SpO2), and pulse rate (PR). These parameters can be displayed periodically for patient monitoring.

The monitor estimates Hct via a calculation based on the Hb measurement for normal hemoglobin values (11 to 17 g/dl) only and abnormal values will not be displayed. It is intended for use by trained medical personnel, with adult individuals, in non-critical clinical and non-clinical settings (e.g. non-critical settings in hospitals, hospital-type facilities, mobile environments, clinics, physician offices and ambulatory surgery centers). In this context, non-critical means patient examination settings where continuous monitoring is unnecessary. Non-critical environments exclude, for example, intensive care units.

Technological Characteristics

The NBM-200 is a portable, non-invasive, Hemoglobin and oximetry monitor for spot checking of hemoglobin (Hb), estimated Hematocrit (Hct), SpO2 and pulse rate. These parameters can be displayed periodically for patient monitoring.

The device is a modification to the cleared NBM-200MP device (K124041). The modified device has the same intended use as the predicate, with the new device's use being limited to non-critical settings, and the two devices use the same technology, main board, finger sensor and algorithm for the calculation of blood parameters. Like the predicate device, the NBM-200 non-invasively spot checks and displays Hemoglobin (Hb) and estimated Hematocrit (Hct) values. The modified device does not measure the NBM-200MP's temporary occluded blood oxygen saturation (SoO2) and plethysmogram waveform. The NBM-200 includes a spot SpO2 and pulse rate measurement, with an optional periodic monitoring function, instead of continuous monitoring of these parameters. The new device's indication and labeling limit use of the device to non-critical care settings. The NBM-200 does not incorporate any alarms, reflecting the device's use in non-critical care environments. The new device has different dimensional specifications of the monitor and display screen, and includes an optional rechargeable battery. The patient/user interface was modified, and software changes were made to accommodate the user interface changes (the algorithm, including the calculation for the parameters, did not change).

Test Data:

The NBM-200 device has been subjected to extensive validation, safety and performance testing before release to ensure that it complies with industry and safety standards. Final testing of the NBM-200 device included safety, environmental and biocompatibility testing according to international industry standards (IEC 62304 and IEC 60601 parts 1 and 1-2), and software validation tests that were designed to ensure that the device meets all its functional specifications.

Bench performance tests were conducted (simulator testing) to ensure that the device meets its accuracy specifications for oximetry (SpO2 and pulse rate).

The NBM-200 sensor probe is identical to that of the NBM-200MP device and its safety was extensively tested in the context of the NBM-200MP submission to FDA.

Clinical Data:

Clinical data for the predicate NBM 200-MP were submitted for the K124041 clearance and no clinical data were generated for the modified device.

Substantial Equivalence:

The NBM-200 pulse oximeter device is substantially equivalent to the NBM 200-MP pulse oximeter and hemoglobin monitor (K124041).